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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,318	02/25/2005	Laurence Gamelin	REGIM 3.3-026	6122

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EXAMINER	
KUDLA, JOSEPH S	
ART UNIT	**PAPER NUMBER**
1609	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,318	GAMELIN ET AL.	
	Examiner	Art Unit	
	Joseph S. Kudla	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/07/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

This application is a 371 of PCT/FR03/00098 (filed January 14, 2003), which claims foreign priority of Foreign Application No. 02/00390 (filed January 14, 2002).

Abstract

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology

often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

1. The abstract of the disclosure is objected to because the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Appropriate action is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 7 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant states in claims 2 and 7 that part of the calcium is in the injectable form and the other part is in oral form. The claim reads as if both forms were present in the same composition at the same time. Applicant needs to clearly state and point out the form the active ingredient exists. In addition, claim 4 recites a completely different "form" of the calcium than is referred to in claims 2 and 7.

Thus, the use of "form" is now even more confusing since claim 4's form is structurally different from claim 2 and 7's form. Further, what form is the active ingredient in?

Claims 3, 5, 9-12 are rejected since they depend from a rejected claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 6 and 8 are rejected under U.S.C. 102(b) as being clearly anticipated by Grolleau et al ("A Possible Explanation for a Neurotoxic Effect of the Anticancer Agent Oxaliplatin on Neuronal Voltage-Gated Sodium Channels," Journal of Neurophysiology, vol. 85, No. 5 pp. 2293-2297, 2001).

Grolleau et al teaches a metabolite of the anticancer agent (title) oxaliplatin is oxalate (page 2293, lines 18-19 of the abstract). Grolleau et al also teaches that the infusion of calcium and magnesium, before and after oxaliplatin administration, oxaliplatin-induced acute neurotoxicity was greatly reduced (page 2297, column 1, last two sentences before references).

3. Claims 1, 3-4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Laine-Cessac et al ("Acute Oxaliplatin Neurotoxicity Dramatically

Improved with Intravenous Calcium and Magnesium Salts," Therapie, Vol. 53 page 183, 1998).

Laine-Cessac et al teaches that the anticancer agent (line 5) oxaliplatin–induced neurotoxicity (1st sentence) can be dramatically improved after simultaneous (patient F/49 in table- given 4 minutes after the start of the 2-hour infusion of oxaliplatin) or post-injection (patient F/59 in table—given 15 minutes after the end of the infusion) administration of calcium and magnesium. Patients were were intravenously administered a mixture of calcium gluconate and magnesium sulfate (1st sentence below table).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laine-Cessac et al ("Acute Oxaliplatin Neurotoxicity Dramatically Improved with Intravenous Calcium and Magnesium Salts," Therapie, Vol. 53 page 183, 1998) in further view of Fox (US PG Publication US 2001/0018082) in further view of Yamamoto et al (US Patent 5,767,149).

Laine-Cessac et al teaches that the anticancer agent (line 5) oxaliplatin–induced neurotoxicity (1st sentence) can be dramatically improved after simultaneous (patient

F/49 in table) or post-injection (patient F/59 in table) administration of calcium and magnesium. Patients were were intravenously administered a mixture of calcium gluconate and magnesium sulfate (1st sentence below table as noted above).

Laine-Cessac et al does not teach the dosage amounts for calcium and magnesium or the administration of both the calcium in oral and parenteral form or that the calcium or magnesium could be administered separately or that that the calcium is administered in the oral and parenteral forms simultaneously.

Fox teaches an oral calcium supplement in the form of an effervescent calcium supplement (title). Within the disclosure, Fox teaches that the primary calcium source for oral delivery is calcium carbonate (paragraph 14) and Fox also teaches calcium chloride (paragraph 26) amongst other calcium salts.

Yamamoto et al teaches the use of ascorbic acid as an antioxidant and physiologically active agent (nutrient) in the pharmaceutical industry (Abstract). In column 18 in Example B-11, last paragraph, Yamamoto teaches that " In use, one bag of the product is dissolved in about 300-500 ml of water, and the solution is favorably useable as an intubation nutrient directed to oral and a parenteral administration to the nasal cavity, stomach and intestine."

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the calcium "part" of the composition could simultaneously be delivered orally and parenterally since Yamamoto makes it clear that a well-known supplement such as ascorbic acid can be administered in both oral and parenteral form.

Although Laine-Cessac et al. does not disclose the dosage ranges set forth in Applicant's instant claim set in claims 5 and 12, the adjustment of particular conventional working dosages is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to realize that if the calcium part is in the solid-oral dosage form and the magnesium is delivered via an injection that the two compounds would be delivered separately because one needs to take one first and then the other.

If one couples the teachings of Laine-Cessac et al. in further view of Fox along with performing a routine optimization of the working ranges of delivery amount for the calcium and magnesium salts, it becomes obvious to one of ordinary skill in the art that the references teach the breath of all of the instant claims applicant asserts as his invention, therefore; claims 1-12 are rejected.

No claims are allowed

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JK

MICHAEL MELLER
PRIMARY EXAMINER